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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,775	06/23/2000	Neil R. Cashman	50111/002002	9735

7590 01/09/2003

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,775	CASHMAN ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The office acknowledges the receipt of the CRF provided by applicant in the response and amendment of April 16, 2002 (Paper No. 12). The CRF has been entered by STIC.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17 and 80, drawn to an antibody, hybridoma cell line producing the antibody and a test kit, classified in class 530, subclass 388.1.

II. Claims 18-24, drawn to a method of detecting prion in a biological sample, classified in class 435, subclass 7.1.

III. Claims 25 and 65-67, drawn to a method of treating or preventing prion disease, classified in class 424, subclass 9.2.

IV. Claims 26-46, 58, 60 and 61, drawn to a peptide, classified in class 530, subclass 300.

V. Claims 47-57 and 59 drawn to a method of generating high affinity antibody to prion protein, classified in class 424, subclass 185.1.

VI. Claims 62-64, drawn to a method of decontaminating a biological sample, classified in class 436, subclass 501.

VII. Claims 68-72 and 74-78, drawn to a method of identifying a compound for treatment or detection of prion disease, classified in class 435, subclass 7.92.

VIII. Claims 73 and 79, drawn to a compound for treatment or detection of prion protein, classified in class 530, subclass 388.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I, IV and VIII are compositions and are distinct from groups II, III and V-VII which are drawn to methods. Groups I, IV and VIII are compositions and each is distinct from the other because they contain different materials. Group I comprises an antibody to the prion protein, although antibodies themselves are proteins, they are different molecules with different structures. Group IV comprises a prion peptide which is made up of amino acids. Group VIII comprises a compound that is identified by a screening method (product by process) and can be any chemical structure. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups II, III and V-VII are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Groups II is drawn t a method of detecting prion protein in a sample. Group III is drawn to a method of treating or preventing prion disease. Group V is drawn to a method of generating hugh affinity antibodies to prion protein. Group VI is a method of decontaminating a biological sample using antibodies. Group VII is drawn to a method of identifying compounds that may treat prion disease. Though there may be overlap between these two methods in question for groups II, III and V-VII, each utilizes different starting materials and techniques and therefore the outcome is expected to be different.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (the antibody) can be used for affinity purification.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case prion disease could be prevented in an animal by creating an animal that has a deletion of the prion gene.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case a antibody to that is specific for the PrP^{Sc} can be made using a phage display library.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the decontamination can be accomplished by subjection the sample to protease degradation.

Inventions VII and VIII are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D. 4/8/03